

DEC 19 1996

DeRoyal Industries, Inc.  
Pelvic Holder

K963465

510(k) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION  
UPON WHICH  
AN EQUIVALENCE DETERMINATION COULD BE BASED

SUBMITTER INFORMATION

NAME: DeRoyal Industries, Inc.  
ADDRESS: 200 DeBusk Lane  
Powell, TN 37849

TELEPHONE: (423) 938-7828  
CONTACT: Camille Matlock  
DATE OF PREPARATION: August 30, 1996

DEVICE NAMES

NAME: DeRoyal Industries, Inc. Pelvic Holder  
COMMON/USUAL NAME: Pelvic Holder  
CLASSIFICATION NAME (if known): Restraint, Protective (80FMQ)

PREDICATE OR LEGALLY MARKETING DEVICES

J.T. Posey Company  
DeRoyal Industries, Inc.

DEVICE DESCRIPTION

The DeRoyal Industries, Inc. Pelvic Holder is a protective restraint device that is intended for medical purposes to limit patient movement thereby enabling examination or protection of the patient or others.

Device Design/Materials Used/Physical Properties: The DeRoyal Pelvic Holder is designed similar to those marketed by other manufacturers. The Pelvic Holder is primarily comprised of either cotton cloth, flannel, cool knit, or cotton sheeting.

DEVICE INTENDED USE

The DeRoyal Industries, Inc. Pelvic Holder is indicated for use, at the discretion of a responsible licensed healthcare professional, to limit patient movement thereby enabling examination or protection of the patient or others. The Pelvic Holder is a protective restraint which can be used with a bed or wheelchair.

TECHNOLOGICAL COMPARISON WITH PREDICATE OR LEGALLY MARKETING DEVICE(S)

Characteristic	DeRoyal Device	Other Devices
Materials	The body is comprised of either cotton cloth, flannel, cool knit, or cotton sheeting	Same
Style Variations	Disposable or Extra Security	Same
Vehicles for Attachment	Bed or Wheelchair	Same
Length of use	Doctor must prescribe every 24 hours	Same
Level of Patient Activity	Mildly Agitated or Disoriented Tendency to Leave Bed or Wheelchair	Same